# Advanced Clinical Monitoring: Considerations for Real-Time Hemodynamic Diagnostics

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## **ABSTRACT**

In an effort to ease staffing burdens and potentially improve patient outcome in an intensive care unit (ICU) environment, we are developing a real-time system to accurately and efficiently diagnose cardiopulmonary emergencies. The system is being designed to utilize all relevant routinely-monitored physiological data in order to automatically diagnose potentially fatal events. The initial stage of this project involved formulating the overall system design and appropriate methods for real-time data acquisition, data storage, data trending, waveform analysis, and implementing diagnostic rules. Initially, we defined a conceptual analysis of the minimum physiologic data set, and the monitoring time-frames (trends) which would be required to diagnose cardiopulmonary emergencies. Following that analysis, we used a fuzzy logic diagnostic engine to analyze physiological data during a simulated arrhythmic cardiac arrest (ACA) in order to assess the validity of our diagnostic methodology. We used rate, trend, and morphologic data extracted from the following signals: expired CO<sub>2</sub> time-concentration curve (capnogram), electrocardiogram, and arterial blood pressure. The system performed well: The fuzzy logic engine effectively diagnosed the likelihood of ACA from the subtle hemodynamic trends which preceded the complete arrest. As the clinical picture worsened, the fuzzy logic-based system accurately indicated the change in patient condition. Termination of the simulated arrest was rapidly detected by the diagnostic engine. In view of the effectiveness of this fuzzy logic implementation, we plan to develop additional fuzzy logic modules to diagnose other cardiopulmonary emergencies.

## **INTRODUCTION**

The morbidity of life threatening events may be adversely affected by any delay in the institution of

corrective measures. Therefore, many patients are intensively monitored in the ICU in order to facilitate the rapid and early diagnosis of these events. Diagnostic delays may be the result of insufficient nurse:patient staffing ratios, dependency upon unsophisticated patient monitor diagnostic and alarm algorithms, and the lack of the capability of current monitoring systems to display the relevant physiologic history.

Usually, critically ill patients are intensively monitored, and it would be ideal if the available physiological signals could be analyzed to provide early detection of impending problems. However, because of the nature and complexity of medical diagnosis, accurate diagnoses are difficult to make using typical computer models. Furthermore, the simplistic signal processing algorithms in general use do not actively exclude noise and other artifact from signal averages, and frequent false alarms are the result. Not only are displayed signal values frequently incorrect, but the erroneous data cannot be used to formulate accurate medical diagnoses. Ideally, we should be able to make more reliable diagnoses by simultaneously monitoring several physiologic signals<sup>2</sup> and implementing newer, more powerful algorithms such as neural networks and fuzzy logic. An advanced comprehensive monitor could be used as a tool to heighten the skills of medical personnel, not merely act as an extension of their skills.3

Some currently-used physiologic signal processing techniques have been effective. For example, several physiologic monitor manufacturers successfully employ conventional signal processing techniques to analyze the ECG. However, when reliably-analyzed signals are not available, we have successfully used neural networks to accurately analyze real-time physiologic waveform data. The neural network method of signal analysis can identify and eliminate artifactual waveforms from the time series, thereby improving the validity of

the data stream and potentially improving the diagnostic reliability of the system.<sup>3,4</sup> Furthermore, a characterization of the waveform morphology can serve as a reliable input into an advanced comprehensive monitoring system.

## **METHODS**

## **Design Considerations**

In order to create a comprehensive monitor capable of performing reliable patient diagnoses, we have a functional set of criteria that must be met by the system. First and foremost, our system must be able to physiologically adapt to individual patients with unique conditions. We cannot realistically expect to use some "normal" baseline as a relative measure of a patient's condition. Therefore, the monitor needs to be informed of the application context (patient age, sex, and medical conditions). Second, if we analyze the signals over multiple time-frames, we can broaden the applicability of the system to disorders which vary in their time course. For example, a given drop in mean blood pressure would have a different diagnostic meaning if the decrease occurred over thirty seconds or thirty minutes. Third, our monitor would need to incorporate an "omniscient" awareness of all signals available. This omniscience allows us to detect the presence of all physiologic signals which are available as inputs, intelligently select the optimal signal sources by eliminating redundant or noisy signals, and optimize the selection of appropriate fuzzy rules in order to exclude the subsets of rules which are dependant on unavailable data. Fourth, performing multiple signal analysis allows us to determine the monitoring context (for example, detection of patient movement artifact). Knowledge of this context then provides us the opportunity to refine the diagnosis. For example, as a patient moves about in bed, movement artifact may distort the ECG waveform and generate an erroneous single-signal diagnosis e.g. ventricular tachycardia. However, simultaneous evaluation of the other available signals (e.g. pulse oximeter plethysmograph, arterial blood pressure waveform) may detect the presence of a normal state. Finally, the monitor needs to record the physiologic history preceding a significant medical event. This historical perspective allows for a more accurate differential diagnosis and subsequently a more effective treatment.

Before design began on the control system, we looked at the dynamics of several diagnoses strictly from a clinical point of view. We selected five specific potentially fatal cardiopulmonary emergencies to generate the system design. The conditions were:

- 1. arrhythmic cardiac arrest (e.g. ventricular fibrillation)
- 2. tension pneumothorax (air surrounding and compressing a lung)
- 3. pericardial tamponade (fluid surrounding and compressing the heart)
- 4. venous air embolism (air in the right ventricle and pulmonary artery)
- 5. exsanguination (severe blood loss)

These five conditions were chosen because they are important, testable, and maximally stress the diagnostic limitations of the system. All of these conditions result in a similar clinical picture of cardiovascular depression which may be difficult to discriminate between. Each of these events can be difficult to diagnose (for a physician, let alone a computer) without constantly and carefully watching all of the physiologic trends. The varying time course of these trends provides diagnostic clues.

Before design began on the control system, we looked at the dynamics of each diagnosis strictly from a clinical point of view. Each of the five medical events were evaluated by examining all of the information that would normally be electronically acquired from each patient, and which could contribute to the diagnosis. For example, a blood pressure monitor can give us mean blood pressure, systolic and diastolic pressure, and heart rate. Other monitored signals include ECG, central venous and pulmonary artery pressures, oxygen saturation by pulse oximetry, airway pressure, systemic arterial pressure, and capnography. Aside from the instantaneous information, an accurate diagnosis depends upon a closer examination of trends which can be assembled from the data. This includes the rate of change for all of the provided information and a classification of each waveform's morphology. For example, from our blood pressure signal we could determine how fast the mean blood pressure was changing (and the direction of change), as well as a waveform classification into categories such as normal, line flush, noise, or damped. We then created a matrix that related the five diagnoses to all of the processed data to help us assess the necessity for each calculated signal

value, and to investigate the rule structure required to diagnose each event. We found that not all of the information is necessary for each diagnosis and each event can have several variations during its onset depending on a patient or environmental context.

Knowing what the system expectations were, we evaluated several types of decision systems to find the most effective and efficient. A traditional rule-based expert system was ruled out because of the known limitations of these systems (discussion below), and the difficulty of changing the rule structure to add additional diagnoses later on.<sup>6</sup> Neural networks would appear to be ideal to recognize these data patterns, however it is difficult (if not impossible) to generate adequate examples to train the network. Fuzzy logic on the other hand, gives us the flexibility to meet all of our initial objectives.<sup>7</sup>

Fuzzy logic is ideal for analyzing rapidly changing variables and classifying data into more than one category. For example, if we look at a classical rule system, a rule could state that if a patient's systolic blood pressure (BPS) is greater or equal to 100 mmHg, then we could classify this pressure as "NORMAL". If BPS was less than 100 mmHg, then we would classify it as "LOW." Now if a person has a BPS of 99 mmHg, then according to the strict rules this person would be classified with "LOW" BPS. In reality, we see that this patient has the characteristics of a pressure that is somewhat low and somewhat normal. This will help us to more accurately describe the true medical condition. Rather than using a classical ruled structure, we can implement a fuzzy logicbased system in order to classify elements into more than one category.<sup>7</sup> This gives us a realistic approach to making a medical diagnosis. With this characterization tool, we can set up a fuzzy logic system to reliably analyze various physiologic trending patterns. We can classify all of our inputs according to ranges from very low to very high and then present our output in the form of a likelihood for the event (e.g. not, somewhat, or very likely). For example, if we wanted to detect ACA, one of our fuzzy rules might look like this: "IF mean blood pressure is Very Low and heart rate is Zero and end tidal CO2 is Very Low THEN the Likelihood of ACA is Very Likely." (Fig. 1 and 2) These rules are not as complex to derive because we created our diagnostic matrix as the foundation for these rules.

A data file was hand-generated using anticipated physiological values consistent with the development ACA in an adult patient. The data set was created for three monitors: ECG, systemic arterial blood pressure, and the capnograph. In addition to the signal amplitude and rate information, a characterization of waveform morphology was generated. ECG complexes were described as "lethal" or "non-lethal". (Lethal ECG

Experimental Diagnosis of Simulated ACA

complexes are defined for the purpose of this experiment as complexes inconsistent with the maintenance of life-sustaining cardiac output.) Capnograms and blood pressure waveforms were described as "normal morphology", "abnormal morphology", or "absent".

The data set began with all signals in the normal range, and progressed to a modest decrease in BPS accompanied by the abrupt appearance of a lethal ECG morphology. Exhaled CO<sub>2</sub> concentration decreased more slowly than BPS as might occur with a mechanical ventilator set to deliver a low minute ventilation. Blood pressure-derived heart rate dropped almost instantaneously to a very low value, whereas the ECG-derived heart rate changed erratically to simulate the ECG monitor's unpredictable analysis of heart rate during ventricular fibrillation. Subsequently, all values approached zero to simulate untreated ACA. After maintaining all values near zero for several seconds, all values were rapidly increased to their lownormal range.

The ACA diagnostic capability of the fuzzy logic rule set was evaluated by reading the prepared data set. The data set was read into a custom Visual Basic program (version 3.0, Microsoft Corp., Redmond, WA) which used a dynamic linked library fuzzy logic tool (CubiCalc RTC version 1.20, Hyperlogic Corp., Escondido, CA) and displayed a graphical representation of the likelihood of ACA over time. The trend of CO2 concentration, BPS, and ECG-derived heart rate were similarly graphed. The relationship of the likelihood of ACA ("not likely", "somewhat likely", or "very likely") was assessed relative to the onset and amount of change of the three input variables.

## RESULTS

Detection of the onset of ACA, evidenced by a transition from "not likely" to a high degree of "somewhat likely", occurred immediately after the

onset of the lethal ECG complex and hypotension. Progression to "very likely" occurred just prior to the nadir of all of the signals and remained in that state until restoration of the circulation. The transition back to a state of "not likely" occurred rapidly: ACA "not likely" was diagnosed as soon as the physiological signals *started* to normalize. Of note was the rapid detection of the onset of ACA, and the smooth transition of the likelihood indicator throughout the event. The performance of the experimental system exceeded our expectations, mainly because of the rapid recognition capabilities.

## CONCLUSION

We have formulated the architecture of a prototype comprehensive cardiopulmonary monitoring system. The system utilizes all available relevant signals from routinely-monitored ICU patients to diagnose and trend the onset and resolution of adverse cardiopulmonary events. Raw signals may be processed by conventional or neural network algorithms to provide reliable data for analyses by fuzzy logic rules. The performance and capabilities of neural network physiologic waveform analysis was evaluated previously<sup>3</sup>, and now the capabilities of utilizing fuzzy logic to analyze this preprocessed data has been studied.

In view of the performance of the ACA-detection module, we plan to continue our development of additional diagnostic modules and perform invivo studies to further evaluate the concepts proposed here. Initial invivo development will require refining the data trending structures, formulating additional fuzzy rules, and evaluating performance of the system on real data. Eventually, system

development will require the long-term collection of ICU patient data in order to capture and analyze adverse events.

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